REMARKS

Reconsideration of the pending claims is requested in light of the remarks below. Entry of these remarks is appropriate as it places the case in better condition for appeal.

I: The Rejection of Claims 1, 2, 4, 8-10 and 17-47 under 35 U.S.C. 112 (written description)

Claims 1, 2, 4, 8-10 and 17-47 stand rejected under 35 U.S.C. 112 as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The Office alleges, without any scientific evidence or reasoning, "2µm-family plasmid" representing a genus of plasmids was not in possession of the Applicant at the time of filing. Applicants traverse this rejection.

Section 112, first paragraph provides that:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same....

The written description requirement of 35 U.S.C. § 112, first paragraph, is fulfilled when the patent specification describes the claimed invention in sufficient detail such that the claim limitations are described so that one of skill in the art would recognize that the applicants had invented the subject matter. See *Vas-Cath, Inc. v. Mahurkar*, 19 U.S.P.Q.2d 1111, 1116 (Fed. Cir. 1991); *In re Herschler*, 591. F.2d 693, 700 (C.C.P.A. 1979). The written description as filed is presumed to be adequate, unless or until sufficient evidence or reasoning to the contrary has been presented by the examiner to rebut the presumption. See *In re Marzocchi*, 169 U.S.P.Q. 367 (CCPA 1971).

The written description requirement can be met by showing that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics, *i.e.*, complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with known or disclosed correlation between function and structure, or some combination of such characteristics. See, e.g., *University of California v. Eli Lilly and Co.*, 43 U.S.P.Q.2d 1398, 1404 (Fed. Cir. 1997); *Enzo Biochem v. Gen-Probe Inc.*, 63 U.S.P.Q.2d 1609, 1613 (Fed. Cir. 2002). A description of a claimed genus may be achieved by recitation of a representative number of species falling within the scope of the genus or by a recitation of structural features

common to the members of the genus which constitute a substantial portion of the genus. See *University of California v. Eli Lilly and Co.*, 43 U.S.P.Q.2d at 1569.

The Patent Office's *Written Description Training Materials*, Revision 1, (March 25, 2008), also provides guidance as to how to determine if there is sufficient written description to inform the artisan that the applicant was in possession of the claimed genus at the time the application was filed. These guidelines instruct that the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species. For example, the Written Description Guidelines expressly state "The number of species required to represent a genus will vary, depending on the level of skill and knowledge in the art and the variability among the claimed genus. For instance, fewer species will be required where the skill and knowledge in the art is high, and more species will be required where the claimed genus is highly variable." See pages 1-2.

The Examiner is incorrect that the use of the term "2µm-family plasmid" does not serve to describe the claimed genus in a manner which allows the species to be distinguished from other plasmids. Initially, Applicants note that he specification describes known 2µm-family plasmid species, including pSR1, pSB3 or pSB4 from the yeast cell *Zygosaccharomyces rouxii*, pSB1 or pSB2 from the yeast cell *Zygosaccharomyces bailli*, pSM1 from yeast cell *Zygosaccharomyces fermentati*, pKD1 from the yeast cell *Kluyveromyces drosophilarum*, pPM1 from the yeast cell *Pichia membranaefaciens, and* the 2µm plasmids from the yeast cell *Saccharomyces cerevisiae* or *Saccharomyces carlsbergensis*. Further, Figure 1 shows a diagram of a 2µm-family plasmid. Any assertion by the USPTO that additional plasmids must be taught or described in the specification is clearly inaccurate. In fact, all 2µm-family plasmids were envisioned by the Applicants in filing the patent application and clearly in the possession of the Applicants. Importantly, the detailed description describes 2µm-family plasmid(s) of the present disclosure beginning on page 7, ln. 1 through page 8, ln. 4. Further, page 6 describes examples of suitable 2µm-family plasmid to be those as described in Volkert *et al*, *Deoxyribonucleic Acid Plasmids in Yeast*, *Microbiological Reviews*, 53(3), 299-317 (1989). Volkert confirms that since the 1980s, a term such as 2µm-family plasmid has been recognized. For example Volkert uses the term 2µm circle like plasmids of Yeast. Utata (1987) futher uses the term "Yeast plasmids resembling 2 µm DNA". Accordingly, the references support the present disclosure that a circular plasmid from yeast is a 2µm-family plasmid.

Moreover, the first paragraph of the specification provides:

> Certain closely related species of budding yeast have been shown to contain naturally occurring circular double stranded DNA plasmids. These plasmids, collectively termed 2μm-family plasmids, include pSR1, pSB3 and pSB4 from *Zygosaccharomyces rouxii* (formerly classified as *Zygosaccharomyces bisporus*), plasmids pSB1 and pSB2 from *Zygosaccharomyces bailii*, plasmid pSM1 from *Zygosaccharomyces fermentati*, plasmid pKD1 from *Kluyveromyces drosphilarum*, an un-named plasmid from *Pichia membranaefaciens* (hereinafter referred to as "pPM1") and the 2μm plasmid and variants (such as Scp1, Scp2 and Scp3) from *Saccharomyces cerevisiae* (Volkert, et al., 1989, Microbiological Reviews, 53, 299; Painting, et al., 1984, *J. Applied Bacteriology*, 56, 331) and other *Saccharomyces* species, such as *S. carlsbergensis*. As a family of plasmids these molecules share a series of common features in that they possess two inverted repeats on opposite sides of the plasmid, have a similar size around 6-kbp (range 4757 to 6615-bp), at least three open reading frames, one of which encodes for a site specific recombinase (such as FLP in 2μm) and an autonomously replicating sequence (ARS), also known as an origin of replication (ori), located close to the end of one of the inverted repeats. (Futcher, 1988, Yeast, 4, 27; Murray et al., 1988, J. Mol. Biol. 200, 601 and Toh-e et al., 1986, *Basic Life Sci.* 40, 425). Despite their lack of discernible DNA sequence homology, their shared molecular architecture and the conservation of function of the open reading frames have demonstrated a common link between the family members. (underlining added for emphasis)

Accordingly, one of ordinary skill in the art would recognize the term 2μm-family plasmid relates to circular yeast plasmids as described in the specification and be able to distinguish them from other plasmids not in the family.

Once apprised of the present disclosure it would be routine for one of ordinary skill in the art to obtain 2μm-family plasmid of the present disclosure. The knowledge in the art is high, in a field where the level of skill in the art is high. Thus, the species mentioned are a representative number of species of 2μm-family plasmid within the scope of the genus and therefore Applicants' disclosure evidences that Applicants were in possession of the claimed genus of plasmids at the time the application was filed.

Moreover, an artisan would reasonably conclude that Applicants were not only in possession of the identified species of 2μm-family plasmid, but also that Applicants had possession of highly related 2μm-family plasmid(s), as specified by the claims. Indeed, based on the high level of skill in the art, the phrase "2μm-family plasmid" itself conveys to the artisan that Applicants were in possession of the claimed invention.

The Examiner has not provided any evidence that one skilled in the art would not be able to identify the claimed plasmids. Indeed, one of ordinary skill in the art would easily be

able to identify a plasmid as a 2μm-family plasmid. Accordingly, Applicants have provided a precise definition of the genus of plasmids sufficient to distinguish it from other plasmids.

In sum, Applicants' specification provides (1) a precise definition by structure of the genus of plasmids sufficient to distinguish it from other plasmids and (2) a description of numerous representative members of the genus, in sufficient detail so that one of skill in the art would recognize that Applicants had invented the claimed subject matter. Further, identifying a species as a 2μm-family plasmid is routine to one of skill in the art, and clearly in Applicants' possession at the time of filing. Accordingly, Applicants respectfully submit that the rejection of claims 1, 2, 4, 8-10 and 17-47 as failing to comply with the written description requirement is in error.

Notwithstanding the above, the Examiner has not provided sufficient evidence or reasoning to rebut that the specification provides an adequate written description for highly related 2μm-family plasmid(s) as claimed. In this regard, additional representative species are not required to be disclosed. Given the high degree of relatedness recited in the claims, an extremely high degree of predictability exists as to the structure and function of the 2μm-family plasmids falling within the claims.

Therefore, Applicants respectfully submit that the specification contains a sufficient description of the structural and functional characteristics of the claimed 2μm-family plasmid(s) to fulfill the requirements of 35 U.S.C. 112. Reconsideration and withdrawal of the rejection are therefore respectfully requested.

II. The Rejection of Claims 1-45, 47 and 64-66 under 35 U.S.C. 112, second paragraph (indefinite)

In the Office action, claims 1-45, 47 and 64-66 were rejected under 35 U.S.C. 112, second paragraph, as indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Examiner contends: 1) "2μm-family plasmid" is unclear. Applicants respectfully traverse.

The essential inquiry for determining indefiniteness is whether the claims set out and circumscribe a particular subject matter with a reasonable degree of clarity and particularity. Definiteness must be analyzed in light of the claim interpretation that would be given by one possessing the ordinary skill in the pertinent art at the time the invention was made. (M.P.E.P. 2173.02) One of ordinary skill in the art would certainly understand that the phrase "2μm-family plasmid" has meaning as described in the throughout the specification. One of skill in the art would further understand how to identify a 2μm-family plasmid. The Examiner's confusion is

difficult to understand as the specification clearly provides a description of the family in the first paragraph:

> Certain closely related species of budding yeast have been shown to contain naturally occurring circular double stranded DNA plasmids. These plasmids, collectively termed 2μm-family plasmids, include pSR1, pSB3 and pSB4 from *Zygosaccharomyces rouxii* (formerly classified as *Zygosaccharomyces bisporus*), plasmids pSB1 and pSB2 from *Zygosaccharomyces bailii*, plasmid pSM1 from *Zygosaccharomyces fermentati*, plasmid pKD1 from *Kluyveromyces drosphilarum*, an un-named plasmid from *Pichia membranaefaciens* (hereinafter referred to as "pPM1") and the 2μm plasmid and variants (such as Scp1, Scp2 and Scp3) from *Saccharomyces cerevisiae* (Volkert, et al., 1989, Microbiological Reviews, 53, 299; Painting, et al., 1984, *J. Applied Bacteriology*, 56, 331) and other *Saccharomyces* species, such as *S. carlsbergensis*. As a family of plasmids these molecules share a series of common features in that they possess two inverted repeats on opposite sides of the plasmid, have a similar size around 6-kbp (range 4757 to 6615-bp), at least three open reading frames, one of which encodes for a site specific recombinase (such as FLP in 2μm) and an autonomously replicating sequence (ARS), also known as an origin of replication (ori), located close to the end of one of the inverted repeats. (Futcher, 1988, Yeast, 4, 27; Murray et al., 1988, J. Mol. Biol. 200, 601 and Toh-e et al., 1986, *Basic Life Sci.* 40, 425). Despite their lack of discernible DNA sequence homology, their shared molecular architecture and the conservation of function of the open reading frames have demonstrated a common link between the family members.

Further, a detailed description describing 2μm-family plasmid(s) of the present disclosure is provided throughout the specification, including but not limited to, page 7, ln. 1 through page 8, ln. 4. See also Volkert *et al*, Deoxyribonucleic Acid Plasmids in Yeast, *Microbiological Reviews*, 53(3), 299-317 (1989) at p306, col. 1, first full paragraph and p312, col. 2, first paragraph. Applicants submit the terminology is clear from the specification. Reconsideration is urged.

Accordingly, Applicants described 2μm-family plasmid in the present disclosure and the term is clear. One of ordinary skill in the art would understand what is meant by 2μm-family plasmid in light of the present disclosure. Reconsideration is urged.

III. Conclusion

The Examiner is hereby invited to contact the undersigned by telephone if there are any questions concerning this amendment or application. Should any additional fees be due the USPTO is authorized to charge the deposit account of Novozymes North America, Inc. *i.e.*, Deposit Account No. 50-1701.

Respectfully submitted,

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